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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,131	09/20/2005	Karen McLachlan	2159.0640004/EKS/PAC/DLL	6721

53644 7590 03/05/2008

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,131	MCLACHLAN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 17 and 36, drawn to an isolated nucleic acid sequence, SEQ ID NO: 2 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 2.

Group II, claim(s) 1, 2, 17 and 37, drawn to an isolated nucleic acid sequence, SEQ ID NO: 4 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 4.

Group III, claim(s) 1, 2, 17 and 38, drawn to an isolated nucleic acid sequence, SEQ ID NO: 6 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 6.

Group IV, claim(s) 1, 2, 17 and 39, drawn to an isolated nucleic acid sequence, SEQ ID NO: 8 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 8.

Group V, claim(s) 1, 2, 17 and 40, drawn to an isolated nucleic acid sequence, SEQ ID NO: 10 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 10.

Group VI, claim(s) 1, 2, 17 and 41, drawn to an isolated nucleic acid sequence, SEQ ID NO: 13 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 13.

Group VII, claim(s) 1, 2, 17 and 42, drawn to an isolated nucleic acid sequence, SEQ ID NO: 15 expressed by human colon cancer cells. Claims 1, 2 and 17 will be examined with this Group to the extent the nucleic acid is SEQ ID NO: 15.

Group VIII, claim(s) 3 and 18, drawn to a primer mixture. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group IX, claim(s) 4-6, drawn to a method of detecting human colon cell by detecting nucleic acid. Claim 4 will be examined with this Group to the extent the method comprises implementing a nucleic acid. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group X, claim(s) 4 and 7-9, drawn to a method of detecting human colon cell antigen by detecting polypeptide. Claim 4 will be examined with this Group to the extent the method comprises implementing an antibody. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group XI, claim(s) 10, 11, 13, 14 and 16, drawn to antigen expressed by human colon cancer cells. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group XII, claim(s) 12, 15, 19 and 20, drawn to a monoclonal antibody that specifically binds to a colon antigen. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group XIII, claim(s) 21, drawn to a method for treating colon cancer, which comprises administering a ribozyme or antisense oligonucleotide that inhibits the expression of a gene having a DNA sequence. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group XIV, claim(s) 22-24, drawn to a method for treating colon cancer, which comprises administering a ligand that specifically binds to a nucleic acid molecule. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group XV, claim(s) 25 and 26, drawn to a method for treating colon cancer comprising administering a colon antigen encoded by a nucleic acid. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

Group XVI, claim(s) 27-35, drawn to a method for treating colon cancer comprising administering a ligand which specifically binds to a protein. Election of this Group requires the further election of a single SEQ ID NO: for reason described below.

2. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: lack the same or

corresponding special technical features for the following reasons:

The special technical feature recited in claim 1 is an isolated nucleic acid comprising a fragment of a nucleotide sequence of SEQ ID NO: 2 having a size of at least 20 nucleotides in length. U.S. Patent number 7,171,311 B2 (effective filing date June 18, 2001) and Accession number AA922292 (May 19, 1998) teaches an isolated nucleic acid comprising a fragment of a nucleotide sequence of SEQ ID NO: 2 having a size of at least 20 nucleotides in length, see alignments below. Therefore, the technical feature recited in claim 1 is not a contribution over the prior art.

```
RESULT 1
US-10-342-887-2073/c
; Sequence 2073, Application US/10342887
; Patent No. 7171311
; GENERAL INFORMATION:
;  APPLICANT: Dai, Hongyue
;  APPLICANT:  He, Yudong
;  APPLICANT:  Linsley, Peter S.
;  APPLICANT:  Mao, Mao
;  APPLICANT:  Roberts, Christopher J.
;  APPLICANT:  Van 't Veer, Laura Johanna
;  APPLICANT:  Van de Vijver, Marc J.
;  APPLICANT:  Bernards, Rene
;  TITLE OF INVENTION: Diagnosis and Prognosis of Breast Cancer Patients
;  FILE REFERENCE: 9301-188-999
;  CURRENT APPLICATION NUMBER: US/10/342,887
;  CURRENT FILING DATE:  2003-01-15
;  PRIOR APPLICATION NUMBER: 60/298,918
;  PRIOR FILING DATE: 2001-06-18
;  PRIOR APPLICATION NUMBER: 60/380,710
;  PRIOR FILING DATE: 2002-05-14
;  PRIOR APPLICATION NUMBER: 10/172,118
;  PRIOR FILING DATE: 2002-06-14
;  NUMBER OF SEQ ID NOS: 2699
; SEQ ID NO 2073
;   LENGTH: 343
;   TYPE: DNA
;   ORGANISM: Homo sapiens
US-10-342-887-2073

  Query Match             48.9%;  Score 332;  DB 5;  Length 343;
  Best Local Similarity   99.7%;  Pred. No. 4.5e-87;
  Matches  343;  Conservative    0;  Mismatches    0;  Indels    1;  Gaps    1;

Qy        333 CATGAAATGTAGAGGGTGAGGCCAAGGAGGACCTGAGAGAAGGTAATTAGATTTGGTGTT 392
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        343 CATGAAATGTAGAGGGTGAGGCCAAGGAGGACCTGAGAGAAGGTAATTAGATTTGGTGTT 284

Qy        393 TACAGGCTGGTCCCTGTGGCCAGCCACCCCACCCACTTTAAAATATTTACTCTACAAATG 452
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                ||||||||||||||||| ||||||||||||||||||||||||||||||||||||||||||||
Db        283 TACAGGCTGGTCCCTG-GGCCAGCCACCCCACCCACTTTAAAATATTTACTCTACAAATG 225

Qy        453 TTAATGTGTGAAGAGTTGCATGCCAGAATATTTATGGCATCAGTGTTGGTGGATACAGAA 512
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        224 TTAATGTGTGAAGAGTTGCATGCCAGAATATTTATGGCATCAGTGTTGGTGGATACAGAA 165

Qy        513 CATTGGGAAACAACCCATTAATAGCAGAATGGTAAATCTGGCCAGTGAATAGTATAGCTT 572
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        164 CATTGGGAAACAACCCATTAATAGCAGAATGGTAAATCTGGCCAGTGAATAGTATAGCTT 105

Qy        573 TTTAAAAGGAGGCTGATGTCTGAATTCACTTTCAAAGTTGTTCACAATGTATTGCTAAAA 632
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        104 TTTAAAAGGAGGCTGATGTCTGAATTCACTTTCAAAGTTGTTCACAATGTATTGCTAAAA 45

Qy        633 TACAAAAATGTTGCAGAACCATATGTATGAGAGAAACCCCTTTT 676
              |||||||||||||||||||||||||||||||||||||||||||||
Db         44 TACAAAAATGTTGCAGAACCATATGTATGAGAGAAACCCCTTTT 1
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RESULT 2
AA922292/c

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LOCUS       AA922292                413 bp    mRNA    linear   EST 19-MAY-1998
ACCESSION   AA922292
VERSION     AA922292.1  GI:3069601
KEYWORDS    EST.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
            Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 413)
ORIGIN
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  Query Match             58.0%;  Score 394;  DB 1;  Length 413;
  Best Local Similarity   99.8%;  Pred. No. 7.4e-94;
  Matches  405;  Conservative    0;  Mismatches    0;  Indels    1;  Gaps    1;

Qy        274 AGTGGAATGAGATCCAGGAGAGGAAGGAGTTTCAGAAGGCAGGAGCTGGTCCTCTATGTC 333
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        413 AGTGGAATGAGATCCAGGAGAGGAAGGAGTTTCAGAAGGCAGGAGCTGGTCCTCTATGTC 354

Qy        334 ATGAAATGTAGAGGGTGAGGCCAAGGAGGACCTGAGAGAAGGTAATTAGATTTGGTGTTT 393
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        353 ATGAAATGTAGAGGGTGAGGCCAAGGAGGACCTGAGAGAAGGTAATTAGATTTGGTGTTT 294

Qy        394 ACAGGCTGGTCCCTGTGGCCAGCCACCCCACCCACTTTAAAATATTTACTCTACAAATGT 453
              ||||||||||||||| ||||||||||||||||||||||||||||||||||||||||||||
Db        293 ACAGGCTGGTCCCTG-GGCCAGCCACCCCACCCACTTTAAAATATTTACTCTACAAATGT 235

Qy        454 TAATGTGTGAAGAGTTGCATGCCAGAATATTTATGGCATCAGTGTTGGTGGATACAGAAC 513
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        234 TAATGTGTGAAGAGTTGCATGCCAGAATATTTATGGCATCAGTGTTGGTGGATACAGAAC 175

Qy        514 ATTGGGAAACAACCCATTAATAGCAGAATGGTAAATCTGGCCAGTGAATAGTATAGCTTT 573
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        174 ATTGGGAAACAACCCATTAATAGCAGAATGGTAAATCTGGCCAGTGAATAGTATAGCTTT 115

Qy        574 TTAAAAGGAGGCTGATGTCTGAATTCACTTTCAAAGTTGTTCACAATGTATTGCTAAAAT 633
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        114 TTAAAAGGAGGCTGATGTCTGAATTCACTTTCAAAGTTGTTCACAATGTATTGCTAAAAT 55

Qy        634 ACAAAAATGTTGCAGAACCATATGTATGAGAGAAACCCCTTTTTCT 679
              |||||||||||||||||||||||||||||||||||||||||||||
Db         54 ACAAAAATGTTGCAGAACCATATGTATGAGAGAAACCCCTTTTTCT 9
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Sequences

3. The multiple sequences listed in claims 1, 4, 10, 11, 14, 21, 22 and 25-27 are subject to further restriction pursuant to 35 U.S.C. 121 and 37 CFR 1.141 as follows. On February 2, 2007 the Commissioner for Patents issued the following notice regarding nucleotide sequences:

> The United States Patent and Trademark Office (Office) published an Official Gazette notice in November of 1996 providing a partial waiver of the requirements for restriction pursuant to 37 CFR 1.141 *et seq.* and for unity of invention determinations pursuant to 37 CFR 1.475 *et seq.* See Examination of Patent Applications Containing Nucleotide Sequences, 1192 Off. Gaz. Pat. Office 68 (Nov. 19, 1996) (1996 Notice). The 1996 Notice permitted examination of a reasonable number, normally up to ten, independent and distinct molecules described by their nucleotide sequence in a single patent application. The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 *et seq.* for restriction practice in national applications filed under 35 U.S.C. 11 I(a), and 37 CFR 1.475 *et seq.* for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications. Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances.

Claim 1 specifically claims numerous nucleic acid molecules identified by SEQ ID NOs. Each sequence is considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct because each sequence has a unique nucleotide sequence and each nucleotide sequence may have a different function. Furthermore, a search of more than one of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one of the claimed sequences. In view of the foregoing, one sequence is considered to be a reasonable number of sequences for examination.

Consequently, upon election of any of Groups I-XVI, applicant is required to elect a single nucleotide sequence or amino acid sequence.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
04 January 2008